

LOS ANGELES, CA 90045

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 10/664,711 09/17/2003 **Budimir Drakulic** RECOM-64412 4390 **EXAMINER** 7590 06/27/2006 ELLSWORTH R. ROSTON, ESQ. LEE, YUN HAENG NMN FULWIDER PATTON LEE & UTECHT, LLP ART UNIT PAPER NUMBER **HOWARD HUGHES CENTER** 6060 CENTER DRIVE, TENTH FLOOR 3766

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
		10/664,711	DRAKULIC, BUDIMIR
	Office Action Summary	Examiner	Art Unit
		Yun H. Lee	3766
The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (8) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
• —	Responsive to communication(s) filed on 21 De		
,—	This action is FINAL . 2b)⊠ This action is non-final.		
3)[Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) Claim(s) 1-77 is/are pending in the application.			
4a) Of the above claim(s) <u>55-77</u> is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6) Claim(s) 1-54 is/are rejected.			
7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.			
O) Claim(o) are easyest to restriction arises a received an entermination			
Application Papers			
9) The specification is objected to by the Examiner.			
10) ☐ The drawing(s) filed on 17 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
Attachment(s)			
1) 🛛 Notic	ce of References Cited (PTO-892)	4) Interview Summary	
3) 🔯 Infor	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date 12/17/04, 12/21/04.	Paper No(s)/Mail D. 5) Notice of Informal F 6) Other:	ate Patent Application (PTO-152)

Application/Control Number: 10/664,711 Page 2

Art Unit: 3766

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-54, drawn to a combination for providing signals at different positions in a patient's heart, classified in class 600, subclass 509.
- II. Claims 55-77, drawn to a method of providing signals at different positions in a patient's heart, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced by hand.
- 3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 4. During a telephone conversation with Ellsworth Roston on 6/21/2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-54. Affirmation of this election must be made by applicant in replying to this Office action. Claims 55-77 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Application/Control Number: 10/664,711 Page 3

Art Unit: 3766

Claim Objections

5. Claims 1-3, 5, 16, 32, 37 and 38 objected to because of numerous informalities, some examples being: In claim 1 line 1, the phrase "in combination" should be changed to "in a combination". In claim 1 line 6, the phrase "the plurality" should be changed to "the plurality of positions" in order to avoid confusion with "the plurality of electrodes". In claim 2 line 2, the phrase "measure V_1 - V_6 positions in the heart" is incorrect since the V_1 - V_6 positions are on the torso not in the heart; a similar error is in claim 3. In claim 5 line 4, the limitation "the production" lacks antecedent basis. In claim 16 line 5, the limitation "the member" lacks antecedent basis; it appears that claim 16 should depend from claim 15 rather than claim 14. In claim 32 line 5, the positions should be in an "upper right portion" and a "lower left portion" instead of an "upper left portion" and a "lower right portion". In claims 37 and 38, the limitation "the rectangle" lacks antecedent basis. Careful proofreading and appropriate correction is required.

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 7-13, 33 and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

Application/Control Number: 10/664,711

Art Unit: 3766

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 7 lines 6-7, the limitation "providing a measurement at an individual one of the positions" does not make sense since the limitation "the positions" refers to positions in the patient's heart as specified in line 2 but the "measurement" occurs at the torso. Regarding claim 33, the specification does not disclose electrodes being disposed in positions in the lower right portion of the vest. Regarding claim 40, the specification does not disclose the positions to be in the upper left portion and the lower right portion of the vest.

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 claims "a plurality of electrodes constructed to be connected to the vest at individual ones of the different positions" where the limitation "the different positions" refers to positions in the patient's heart as specified in line 2. It is indefinite to claim to connect to the vest at individual ones of the different positions when the different positions refer to positions in the patient's heart and not to positions in the vest.
- 10. Claims 27, 28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: an inflator.

Art Unit: 3766

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45, 47, 49-54 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Examiner finds Applicant's claim of an amplifier not producing any noise to be incredible.

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 1-6, 19-24, 29, 30, 32-39, 44, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330).

Regarding claim 1, Greene clearly anticipates the claimed invention except for the amplifiers. Examiner takes Official Notice that it is extremely old and well known to use amplifiers when dealing with biological signals in order to reduce noise, buffer signals and provide a gain or amplitude increase. Thus, it would have been obvious to one of ordinary skill in the art to use amplifiers responsive to the signals on the electrodes at the individual positions in the vest of Greene.

Application/Control Number: 10/664,711

Art Unit: 3766

Regarding claim 2, Examiner takes Official Notice that the V_1 - V_6 positions, as part of the standard 12 lead electrocardiogram, are extremely old and well known in the art for obtaining spatial information about the heart's electrical activity. Thus, it would have been obvious to one of ordinary skill in the art to position the electrodes of Greene at the positions V_1 - V_6 .

Regarding claim 3, the limitations are met by the above discussion.

Regarding claim 4, Greene clearly shows a grid consisting of rows and columns.

Regarding claims 5, 23, 24, 46, 48, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding claims 6, 19-22, 29, 30, 44, the limitations are met by the above discussion.

Regarding claims 32-39, the various claimed electrode configurations are simply in accordance with a conventional 12 lead electrocardiogram configuration which is old and well known as discussed above. Thus, the limitations are met by the above discussion.

Art Unit: 3766

14. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330) in view of the above discussion and further in view of Heilman et al. (US Pat. No. 5,078,134). Heilman et al. discloses an inflator (322) for inflating a vest against the patient's body to reduce the impedance at the electrode/skin interface (col. 12 lines 20-21). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include an inflator in the vest of Greene for inflating the vest against the patient's body to reduce the impedance at the electrode/skin interface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/664,711 Page 8

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000,

Robert Pezzuto

Supervisory Patent Examiner

Art Unit 3766

yhl